UPAP0003-100 (136622)

Application Serial No.: 10/076,900

Response to Official Action dated August 23, 2004

Amendment After Final Rejection and Reply dated February 23, 20052003

## Amendments to the Claims:

Please cancel claim 92.

Claims 1-14 (Canceled)

15. (Previously Presented) A method of inducing in an individual an immune response against an antigen

wherein said immune response includes both a humoral immune response that includes a mucosal immune response and a cellular immune response that includes antigen specific cytotoxic T lymphocytes;

the method comprising the step of administering by topical or lavage administration to sublingual mucosal tissue of said individual, a nucleic acid molecule that is free of an infectious agent and comprises a nucleotide sequence that encodes said antigen operably linked to regulatory sequences in an amount effective to induce an immune response against said antigen wherein said immune response includes both a humoral immune response that includes a mucosal immune response and a cellular immune response.

16. (Previously Presented) The method of claim 15 wherein the antigen is a pathogen antigen.

Claims 17-38 (Canceled)

- 39. (Previously Presented) The method of claim 15 wherein the immune response is a therapeutically effective immune response and said nucleic acid molecule is administered in an amount effective to induce a therapeutically effective immune response against said antigen.
- 40. (Previously Presented) The method of claim 39 wherein the antigen is a pathogen antigen.
- 41. (Previously Presented) The method of claim 40 wherein the pathogen antigen is a viral antigen.

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Amendment After Final Rejection and Reply dated February 23, 20052003

42. (Previously Presented) The method of claim 41 wherein the viral antigen is an antigen from human immunodeficiency virus.

- 43. (Previously Presented) The method of claim 42 wherein antigen from human immunodeficiency virus comprises an epitope of human immunodeficiency virus protein gp160.
- 44. (Previously Presented) The method of claim 43 wherein said nucleic acid molecule is administered to said individual in a composition that further comprises bupivacaine.
- 45. (Previously Presented) The method of claim 15 wherein the immune response is a prophylactically effective immune response and said nucleic acid molecule is administered in an amount effective to induce a prophylactically effective immune response against said antigen.
- 46. (Previously Presented) The method of claim 45 wherein the antigen is a pathogen antigen.
- 47. (Previously Presented) The method of claim 46 wherein the pathogen antigen is a viral antigen.
- 48. (Previously Presented) The method of claim 47 wherein the viral antigen is an antigen from human immunodeficiency virus.
- 49. (Previously Presented) The method of claim 48 wherein antigen from human immunodeficiency virus comprise an epitope of human immunodeficiency virus protein gp160.
- 50. (Previously Presented) The method of claim 49 wherein said nucleic acid molecule is administered to said individual in a composition that further comprises bupivacaine.
- 51. (Previously Presented) The method of claim 16 wherein the pathogen antigen is a viral antigen.
- 52. (Previously Presented) The method of claim 51 wherein the viral antigen is an antigen from human immunodeficiency virus.

Response to Official Action dated August 23, 2004

Amendment After Final Rejection and Reply dated February 23, 20052003

53. (Previously Presented) The method of claim 52 wherein antigen from human immunodeficiency virus comprise an epitope of human immunodeficiency virus protein gp160.

54. (Previously Presented) The method of claim 53 wherein said nucleic acid molecule is administered to said individual in a composition that further comprises bupivacaine.

Claims 55-80. (Canceled)

- 81. (Previously Presented) The method of claim 15 wherein said nucleic acid molecule is administered to said individual in a composition that comprises a nucleic acid molecule which comprises a nucleotide sequence that encodes: a cytokine operatively linked to regulatory sequences which control the expression of said nucleotide sequence; and/or a nucleotide sequence that encodes a lymphokine, said nucleotide sequence operatively linked to regulatory sequences which control the expression of said nucleotide sequence.
- 82. (Previously Presented) The method of claim 81 wherein said composition comprises bupivacaine.
- 83. (Previously Presented) The method of claim 81 wherein said composition comprises a nucleic acid molecule which comprises a nucleotide sequence that encodes a protein operatively linked to regulatory sequences which control the expression of said nucleotide sequence, wherein said protein is selected form the group consisting of .alpha.-interferon, gamma-interferon, platelet derived growth factor (PDGF), GC-SF, GM-CSF, TNF, epidermal growth factor (EGF), IL-1, IL-2, IL-4, IL-6, IL-8, IL-10 and IL-12.
- 84. (Previously Presented) The method of claim 83 wherein said composition comprises bupivacaine.
  - 85. (Previously Presented) The method of claim 83 wherein said protein is IL-12.
- 86. (Previously Presented) The method of claim 85 wherein said composition comprises bupivacaine.

Response to Official Action dated August 23, 2004

Amendment After Final Rejection and Reply dated February 23, 20052003

87. (Previously Presented) The method of claim 16 wherein said nucleic acid molecule is administered to said individual in a composition that comprises a nucleic acid molecule which comprises a nucleotide sequence that encodes: a cytokine operatively linked to regulatory sequences which control the expression of said nucleotide sequence; and/or a nucleotide sequence that encodes a lymphokine, said nucleotide sequence operatively linked to regulatory sequences which control the expression of said nucleotide sequence.

- 88. (Previously Presented) The method of claim 87 wherein said composition comprises bupivacaine.
- 89. (Previously Presented) The method of claim 87 wherein the pathogen antigen is a viral antigen.
- 90. (Previously Presented) The method of claim 89 wherein the viral antigen is an antigen from human immunodeficiency virus.
- 91. (Previously Presented) The method of claim 90 wherein antigen from human immunodeficiency virus comprise an epitope of human immunodeficiency virus protein gp160.

## Claim 92. (Canceled)

- 93. (Previously Presented) The method of claim 87 wherein said composition comprises a nucleic acid molecule which comprises a nucleotide sequence that encodes a protein operatively linked to regulatory sequences which control the expression of said nucleotide sequence, wherein said protein is selected form the group consisting of .alpha.-interferon, gamma-interferon, platelet derived growth factor (PDGF), GC-SF, GM-CSF, TNF, epidermal growth factor (EGF), IL-1, IL-2, IL-4, IL-6, IL-8, IL-10 and IL-12.
- 94. (Previously Presented) The method of claim 93 wherein said composition comprises bupivacaine.
- 95. (Previously Presented) The method of claim 93 wherein the pathogen antigen is a viral antigen.

Response to Official Action dated August 23, 2004

Amendment After Final Rejection and Reply dated February 23, 20052003

96. (Previously Presented) The method of claim 95 wherein the viral antigen is an antigen from human immunodeficiency virus.

- 97. (Previously Presented) The method of claim 96 wherein antigen from human immunodeficiency virus comprise an epitope of human immunodeficiency virus protein gp160.
- 98. (Previously Presented) The method of claim 97 wherein said composition comprises bupivacaine.
  - 99. (Previously Presented) The method of claim 93 wherein said protein is IL-12.
- 100. (Previously Presented) The method of claim 99 wherein said composition comprises bupivacaine.
- 101. (Previously Presented) The method of claim 99 wherein the pathogen antigen is a viral antigen.
- 102. (Previously Presented) The method of claim 101 wherein the viral antigen is an antigen from human immunodeficiency virus.
- 103. (Previously Presented) The method of claim 102 wherein antigen from human immunodeficiency virus comprise an epitope of human immunodeficiency virus protein gp160.
- 104. (Previously Presented) The method of claim 103 wherein said composition comprises bupivacaine.
- 105. (Previously Presented) The method of claim 16 wherein said composition comprises bupivacaine.
- 106. (Previously Presented) The method of claim 105 wherein the pathogen antigen is a viral antigen.
- 107. (Previously Presented) The method of claim 106 wherein the viral antigen is an antigen from human immunodeficiency virus.